Multicenter Validation of an ECG and Oxygen Saturation Based Sleep Diagnostic System

Clement Cahan¹, Michael J. Decker²,³, Shuli Eyal⁴, Zvika Shinar⁴, Armanda Baharav⁴, William C. Reeves³
(1) Shaare Zedek Medical Center, Sleep Disorders Clinic, Israel; (2) Fusion Sleep – Program in Sleep Disorders, Suwanee, GA, USA;
(3) Centers for Disease Control & Prevention, Atlanta, GA, USA; (4) HypnoCore, Netanya, Israel.

Introduction
➢ Sleep Related Breathing Disorders (SBD) affect 2-4% of the adult population and are treatable, yet 82% of men and 93% of women are believed to remain undiagnosed.¹ ²
➢ SBD have been associated with systemic hypertension, significant cardiovascular morbidity and increased mortality.³
➢ Simple, reliable, user friendly and cost effective diagnostic procedures represent a burning need.
➢ The purpose of this study is the validation of an alternative diagnostic system that relies on ECG and pulse oximetry signals to diagnose Obstructive Sleep Apnea (OSA), the HC1000P system by HypnoCore.

Methods
➢ The HC1000P:
   ➢ Detects respiratory events by oximetry and ECG morphology (ECG Derived Respiration-EDR).⁴ ⁵
   ➢ In addition the system can identify sleep architecture, arousals and awakenings. This is based on the connection between sleep and differential autonomic nervous system modulation of instantaneous heart rate⁶ during different sleep stages.⁷
➢ In this blinded, multi-center retrospective study we compared the automated application of HC1000P to results obtained by the gold standard, manual method using Rechtschaffen & Kales and ASDA scoring criteria.
➢ 104 recordings were used in this study:
   ➢ 54 were randomly selected from a cohort Chronic Fatigue Syndrome study for the CDC in Wichita, Kansas. The patients were screened to exclude OSA.
   ➢ 50 were consecutive studies of patients referred for PSG for suspected OSA at Shaare Zedek Medical Center in Jerusalem.
   ➢ Age: 48.6 ± 14.0 (Range: 19 – 79)
   ➢ BMI: 29.3 ± 5.8 (Range: 18 – 48)
   ➢ Male/Female: 47/57
➢ The ECG and pulse oximetry signals were separately analyzed by the HC1000P, to determine the respiratory disturbance index (RDI), sleep time, sleep efficiency, the time spent awake, and NREM, REM sleep, awakenings and arousals.
➢ Inclusion criteria: recording time of at least 5 hours, normal sinus rhythm and good quality ECG and oximetry signals.
➢ The purpose of this study is the validation of an alternative diagnostic system that relies on ECG and pulse oximetry signals to diagnose Obstructive Sleep Apnea (OSA), the HC1000P system by HypnoCore.

Results
Respiratory evaluation:
➢ The desaturations found by the HC1000P system and those found by manual gold standard scoring correlate highly, with R = 0.97, as can be seen in Figure 1(a). The Bland-Altman plot in Figure 1(b) shows the good agreement between results obtained by the two methods.
➢ The total number of respiratory events highly correlated between the two methods with R = 0.92.
➢ RDI (apneas/hypopneas per hour of sleep) highly correlated with R = 0.90 as can be seen in Figure 2.

Sleep architecture comparison:
➢ Results of the analysis show good overall agreement with regards to total sleep time (TST), sleep efficiency, percentage of time spent in REM and NREM sleep as seen in Figure 3. The number of arousals detected by the two methods was also highly correlated.

Conclusions
➢ The HC1000P allows for an accurate, specific and highly sensitive method to diagnose Obstructive Sleep Apnea (OSA).
➢ As opposed to other partial tests, the HC1000P gives insight into sleep architecture.
➢ Results are accurate even at low RDIs, i.e. mild cases of OSA or normal individuals. This implies it can be used as a true diagnostic tool, not just a method of screening.
➢ The simplicity of the method allows for easy follow up studies which are not affordable by standard methods. Thus, compliance with CPAP might increase.
➢ It is a cost-effective measure for mass diagnosis, of great importance for a disorder with a high prevalence of undiagnosed cases.

References